

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code section 147.76, the Board of Pharmacy hereby amends Chapter 13, “Sterile Compounding Practices,” Iowa Administrative Code.

The amendment provides for an exception for the placement of a compounding aseptic isolator (CAI) within an ISO Class 8 anteroom or ante area when the CAI meets ISO Class 5 atmospheric environment conditions.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the November 3, 2010, Iowa Administrative Bulletin as **ARC 9187B**. The Board received no written comments regarding the proposed amendment. The adopted amendment is identical to that published under Notice.

The amendment was approved during the January 11, 2011, meeting of the Board of Pharmacy.

This amendment will become effective on April 13, 2011.

This amendment is intended to implement Iowa Code sections 126.10, 155A.2, 155A.13, and 155A.28.

The following amendment is adopted.

Amend subrule 13.27(4) as follows:

13.27(4) Anteroom requirements. ~~An~~ Except for a CAI that meets the conditions specified in subrule 13.27(3) exempting the CAI from placement in an ISO Class 7 cleanroom, an anteroom or ante area shall be located adjacent to the buffer area and maintained at ISO Class 8 air quality. This area is to be used for unpacking and disinfecting supplies for storage and for hand sanitizing and gowning. If the sterile preparation area is to be used only for the compounding of low- and medium-risk preparations, the ante area shall be clearly demarcated for the compounding of low- and medium-risk preparations. If the sterile preparation area is to be used for the compounding of high-risk preparations, the ante area shall be physically separated from the buffer area.

[Filed 2/15/11, effective 4/13/11]

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 3/9/11.